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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/622,776 | 08/23/2000 | John Bureczak | DEX-0079 | 2610 |

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/622,776

Applicant(s)

BURCZAK ET AL.

Examiner

Susan Ungar

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires four months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☒ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.


The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: none.Claim(s) rejected: 11, 12 and 16.Claim(s) withdrawn from consideration: none.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

10. ☐ Other: _____


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

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1. The Amendment-after-Final filed March 5, 2004 in response to the Office Action of November 5, 2003 is acknowledged and has been entered. Claims 11, 12, 16 are currently under prosecution.
2. The following rejections are maintained:

Claim Rejections - 35 USC § 103

3. Claims 11-12 and 16 remain rejected under 35 USC 103 for the reasons previously set for in the paper mailed November 5, 2003, Section 4, pages 2-4.

Applicant argues that Funkakoshi et al (Pancreas, 1991, 6(5):588-594 teaches that serum PLA2 levels were within normal range in patients with malignant tumors other than pancreatic cancer and points to the abstract and Figure 1 and Applicant concludes that this reference provides objective evidence that serum PLA2 concentrations are not nor would be expected by the skilled artisan to be elevated in a subset of all carcinomas.

The argument has been considered but has not been found persuasive because although a review of the abstract reveals that Applicant is accurately reporting the information in the abstract, a review of Figure 1 (which clearly delineates the normal range for PLA2) clearly demonstrates that a subset of those with “other cancers” overexpress PLA2 compared to normal control and that at least 30% of the 45 patients with hepatocellular carcinoma overexpress PLA2 compared to normal control. Contrary to Applicant’s arguments, the submitted reference provides additional evidence of the obvious nature of the invention.

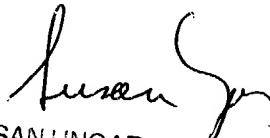
Applicants disagree with Examiner’s suggestion at page 2 of the Office Action that the claims are not drawn to monitoring. Examiner has reviewed the claims and it is clear that the claims are drawn to monitoring. Examiner apologizes for any inconvenience. However, although Examiner stated that arguments

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relating to these limitations as distinguishing the present invention from the cited prior art are not relevant, Examiner did go on to state that, for the reasons of record, it would be obvious to use the expression levels of PLA2 to monitor the progression, remission or response to therapy of ovarian or testicular cancers.

Applicant further argues that since the prior art fails to provide any reasonable expectation of success and fails to teach or suggest all the limitations of the claimed invention, no *prima facie* case of obviousness has been established.

The argument has been considered but has not been found persuasive since the submitted reference clearly demonstrates that subsets of various cancers do indeed overexpress PLA2 and for the reasons of record, the claimed invention is obvious.



SUSAN LINGAR, PH.D.
PRIMARY EXAMINER